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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,736	03/23/2004	Jerome David	SPINE 3 . 0-423	2555
530 7590 12/26/2007 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			EXAMINER SHAFFER, RICHARD R	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 12/26/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/806,736	<b>Applicant(s)</b> DAVID, JEROME	
	<b>Examiner</b> Richard R. Shaffer	<b>Art Unit</b> 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 October 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 and 28-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 and 28-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

The amendments to the claims filed on October 9<sup>th</sup>, 2007 are acknowledged and accepted by the examiner. The previous 35 U.S.C. 112, first and second paragraph rejections are overcome and are hereby withdrawn.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-26 and 28-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Independent **claim 1** now recites, "...allowing the **stopping element** and the bone fastener **to be positioned** and locked in the **sliding element aperture**..."

Applicant does not have support in the specification as originally filed for the stopping element to be positioned in the sliding element aperture. Rather, the sliding element is within the stopping element's aperture as can be seen in **Figure 1**. **Claim 25** suffers from the same new matter except uses the language "positioning means" and "insert." **Claim 30** also is the same, but recites "positioner" and "insert."

All dependent claims have been rejected for containing new matter through inheritance.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 5-7, 9-26 and 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shluzas et al (US Patent Application Publication 2002/0143328) in view of Kambin (US Patent 5,964,761) and further evidenced by Petit et al (US Patent Application Publication 2003/0045878).

Shluzas et al disclose a bone plate system (**Figure 5**) comprising: a curved (see **Figure 3**) bone plate (**212**) having a first aperture (**250**), second aperture (**252**), and a third aperture (**254**) extending along a longitudinal axis and having an upper and lower surface; a sliding element having a top (**242**) and bottom (**270**) portion, an aperture extending along a central axis, the top portion having a compression member (lower portion of top **242**), the bottom portion having a locking member (upper portion of **270**), both the top and bottom portions having inwardly tapered walls (the top is internal, the bottom is external at the base where it interfaces with **240**), both portion have a radially outward extending shoulder (**286** and **294**), and both portions interact with an interior wall of the bone plate aperture (**250**); a bone fastener (**216**) having a longitudinal axis, stem which is orientated within the sliding element aperture; a stopping element (**240**); a threaded locking element (**228**) having a bore for receiving the stem of the bone screw and includes a concave base (**206**) and a cap (more easily seen in **Figure 3**). In

**Column 5, Paragraph 57**, it is further disclosed that the stopping element could have a convex surface with the bottom element having a concave surface to interact.

Shluzas et al disclose all of the claimed limitations except for the stopping element being separable and adjustable by threading as well as the method of doing so.

Kambin teaches (**Figures 6 and 7; Column 3, Lines 1-31; Column 6, Lines 43-58**) a mechanism through the use of a sleeve (**70**) that adjusts the effective height of the screw in order to appropriately place bone plate (**104**) adjacent the fascia but under the skin. It would have been obvious to one having ordinary skill in the art at the time the invention was made to consider the design benefits of having an adjustable screw for proper bone plate placement. It has further been held that that the provision of adjustability, where needed, involves only routine skill in the art. *In re Stevens*, 101 USPQ 284 (CCPA 1954).

One having ordinary skill in the art at the time of invention would have had at least two equally obvious design choices in how to provide the adjustability. One would have been merely separating element **32** from Shluzas and providing internal threading like the sleeve **70** of Kambin while leaving element (**34**) intact to provide for the previous driver engagement. The other would have been following the teaching of Petit et al demonstrating no such driver engagement (**except for at the head {5, Figure 2}**) therefore allowing the entire complex of **32** and **34** of Shluzas to be modularly adjustable along the shaft of the screw through a threaded engagement. The level of skill required has been deemed to be within that of an ordinary worker in the art; see *Nerwin v. Erlichman*, 168 USPQ 177, 179.

Claims 3, 4 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shluzas et al in view of Kambin, further evidenced by Petit et al, and further in view of Lin (US Patent 5,613,968).

Shluzas et al in view of Kambin and Petit et al disclose and teach all of the claimed limitations except for the top portion having a plurality of tapered fingers with a ridge at least partially around an outer circumference to engage a lip around an inner circumference of the base portion. Lin teaches (**Figure 3c**) an insert with a ridge (to engage a lip) with a plurality of tapered (**240** demonstrated a tapered direction) fingers (slots **250** define them) to assure quick and reliable interconnection. One having ordinary skill in the art at the time of invention would have readily appreciated the obvious ability of modifying the top and bottom portions of Shluzas et al to accept a fingered top portion with a ridge to snap-fit into a lower base portion in order to provide for a reliable connection with a tactile and audible notification to the practitioner performing the surgery.

### ***Response to Arguments***

Applicant's arguments filed October 9<sup>th</sup>, 2007 have been fully considered but they are not persuasive. In regard to the newly added limitation of each independent claim, clearly the stopping element and bone fastener of the combinations allow for a plurality of different angles while being locked within the sliding element/insert. Applicant may not however be readily appreciating that the stopping element does rotate about an "exterior wall" of the base portion. The surface is still an external or on the exterior of the element and therefore can be reasonably interpreted as an exterior wall.

Applicant is encourage to contact the examiner in the future in order to craft language which does not include new matter and will overcome the prior art of record.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

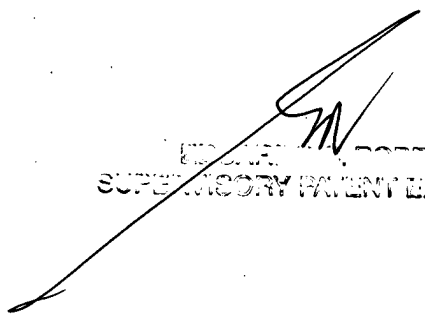
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*Richard Shaffer*

Richard Shaffer  
December 15<sup>th</sup>, 2007

  
ROBERT M. [unclear]  
SUPERVISORY PATENT EXAMINER